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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,203	07/29/2003	Thomas Thisted	10062.210-US	1994

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NOVOZYMES NORTH AMERICA, INC.
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EXAMINER

PROUTY, REBECCA E

ART UNIT	PAPER NUMBER
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1652

MAIL DATE	DELIVERY MODE
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10/15/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/630,203

Applicant(s)

THISTED ET AL.

Examiner

Rebecca E. Prouty

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period **will** apply and **will** expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply **will**, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 41, 43- 49, and 51-57 is/are pending in the application.
- 4a) Of the above claim(s) 45 and 57 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 41, 43, 44, 46-49 and 51-56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

Art Unit: 1652

Claims 1-40, 42, and 50 have been canceled. Claims 41, 43-49, and 51-57 are at issue and are present for examination.

Applicant's election with traverse of Group II, Claims 41, 43, 44, 46-49, and 51-56, drawn to a variant of an alpha-amylase, wherein the variant comprises an amino acid sequence having at least 90% homology to SEQ ID NO:8 and consisting of a substitution at a position corresponding to position 170 and a substitution at a position corresponding to position 49 in SEQ ID NO:8, and wherein the variant has alpha-amylase activity, in the reply filed on 8/5/08 is acknowledged. The traversal is on the ground(s) that all claims are not difficult to search using modern search techniques, thus it would not be a burden on the USPTO to examine and/or search these claims. This is not found persuasive because the search of each independent position to be modified in a variant protein is distinct and modern techniques do NOT provide for one to look for multiple positions simultaneously as the disclosure of variant proteins is seldom searched by sequence search techniques, the search of each position is complicated by the fact that the corresponding positions of related proteins frequently have different position numbers (for example position 170 of SEQ ID NO:8 herein is equivalent to position 172 of SEQ ID NO:4 herein) such that one cannot simply search for particular numbers and art teaching

Art Unit: 1652

modification of one position does not make *prima facie* obvious modification of other positions. As such search of many additional positions to be modified would in fact be an enormous additional burden on the examiner.

The requirement is still deemed proper and is therefore made FINAL.

Claims 45 and 57 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 8/5/08.

Claims 46, 51 and 56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 46 is confusing in the recitation of "wherein the variant is derived from a strain of *B. licheniformis*" as the variants recited are non-naturally occurring proteins and thus cannot be isolated from a strain of *B. licheniformis*. It is presumed that applicants intended "wherein the variant is derived from a *Bacillus licheniformis* alpha-amylase".

Claim 51 is confusing in the recitation of "A variant of an alpha-amylase, wherein the variant comprises ... and a

Art Unit: 1652

substitution of a Q at a position corresponding to position 170 in SEQ ID NO:8" as it is unclear if this means that a Q residue in the parent enzyme is to be replaced or if the residue which is substituted is replaced with a Q residue. It is presumed that applicants intended "A variant of an alpha-amylase, wherein the variant comprises ... a substitution of the residue at the position corresponding to position 170 in SEQ ID NO:8 with a Q residue".

Claim 56 is confusing in the recitation of "A variant *Bacillus licheniformis* alpha-amylase, wherein the variant comprises ... an alteration of a Q at a position corresponding to position 170 in SEQ ID NO:8" as position 170 of *Bacillus licheniformis* alpha-amylase is a lysine residue (K) not a glutamine (Q) residue. It is presumed that applicants intended "A variant *Bacillus licheniformis* alpha-amylase, wherein the variant comprises ... a substitution of the residue at position corresponding to position 170 in SEQ ID NO:8 with a Q residue".

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an

Art Unit: 1652

application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 41, and 46-49 are rejected under 35 U.S.C. 102(e) as being anticipated by Andersen et al. (US PG-PUBS 2003/0129718).

The applied reference has a common inventor and assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Andersen et al. teach α -amylase variants in which the amino acid corresponding to position 170 of *Bacillus licheniformis* α -amylase (SEQ ID NO:8 of the instant application) in any Termamyl-like α -amylase replaced with a different amino acid. Andersen et al. also teach modification of other amino acid positions including at least positions corresponding to positions 180, 181, and 183 from the large group recited in the claims. (see for example paragraphs [0379], [0380], and [0390],

Art Unit: 1652

in which it is noted that positions 172, 185, 186, and 188 of the AA560 amylase correspond to positions 170, 180, 181, and 183 of SEQ ID NO:8). Andersen et al. further teach that a preferred parent alpha amylase is that of *Bacillus licheniformis* (see paragraph [0089], i.e., the alpha amylase of SEQ ID NO:8 herein) and thus a variant of BLA modified only at position 170 and one of 180, 181, or 183 would have greater than 99% identity to SEQ ID NO:8.

Applicants submitted a declaration under 37 CFR 1.132 which states that Carsten Andersen is the inventor of the subject matter from US PG-PUBS 2003/0129718 which is relied upon in the rejection. Thus, the subject matter relied upon in US PG-PUBS 2003/0129718 is not "by another," and is therefore not prior art to the instant application. However, this is not persuasive as Carsten Andersen is not the sole inventor of the instant application and thus the reference cited remains "by another". No evidence of distinct inventorship of individual claims of the instant application has been filed. As such the inventive entity of the application as filed is presumed to be the inventive entity of all claims herein.

Claims 41, 44, and 46-49 rejected under 35 U.S.C. 102(b) as being anticipated by Borchert et al. (WO 99/23211).

Art Unit: 1652

Borchert et al. teach α -amylase variants in which the amino acid corresponding to position 170 of *Bacillus licheniformis* α -amylase (SEQ ID NO:8 of the instant application) in any Termamyl-like α -amylase is replaced with a different amino acid. Borchert et al. also teach modification of other amino acid positions including at least positions corresponding to positions 179, 180, and 181 from the large group recited in the claims. (see for example page 6, in which it is noted that positions 172, 184, 185, and 186 of the SP722 amylase correspond to positions 170, 179, 180, and 181 of SEQ ID NO:8). Borchert et al. further teach that a preferred parent alpha amylase is that of *Bacillus licheniformis* (see page 13, i.e., the alpha amylase of SEQ ID NO:8 herein) and thus a variant of BLA modified only at position 170 and one of 179, 180, and 181 would have greater than 99% identity to SEQ ID NO:8.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered

Art Unit: 1652

therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 43 and 51-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Andersen et al. (US PG-PUBS 2003/0129718).

Andersen et al. teach α -amylase variants in which the amino acid corresponding to position 170 of *Bacillus licheniformis* α -amylase (SEQ ID NO:8 of the instant application) in any Termamyl-like α -amylase is replaced with a different amino acid. However, Andersen et al. do not explicitly teach what amino acid position 170 should be replaced with. However, a skilled artisan would have found it obvious given the teaching of Andersen to modify this position to replace the naturally occurring amino acid with all other 19 naturally occurring amino acids. Furthermore, as inspection of the alignment of Termamyl-like α -amylases of Figure 1 of Andersen et al. shows that in some naturally occurring Termamyl-like α -amylases, this position is occupied with a glutamine residue, it would have been obvious to one of ordinary skill in the art to select glutamine as the amino acid to replace position 170 with as a skilled artisan

Art Unit: 1652

would reasonably expect that the three-dimensional structure of Termamyl-like α -amylases would accommodate a glutamine at this position.

Claims 41, 44 and 46-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Borchert et al. (WO 99/23211) in view of Andersen et al. (US Patent 6,410,295).

Borchert et al. teach α -amylase variants in which the amino acid corresponding to position 170 of *Bacillus licheniformis* α -amylase (SEQ ID NO:8 of the instant application) in any Termamyl-like α -amylase is replaced with a different amino acid. Borchert et al. also teach modification of other amino acid positions. Borchert et al. further teach that a preferred parent alpha amylase is that of *Bacillus licheniformis* (see page 13, i.e., the alpha amylase of SEQ ID NO:8 herein) and thus a variant of BLA modified only at position 170 and another position would have greater than 99% identity to SEQ ID NO:8.

Andersen et al. teach α -amylase variants in which the amino acid corresponding to position 49 of *Bacillus licheniformis* α -amylase (SEQ ID NO:8 of the instant application) in any Termamyl-like α -amylase is replaced with a different amino acid preferably T49I (see column 6). Andersen et al. also teach modification of other amino acid positions. Andersen et al.

Art Unit: 1652

further teach that a preferred parent alpha amylase is that of *Bacillus licheniformis* (see page 13, i.e., the alpha amylase of SEQ ID NO:8 herein)

As each of Borchert et al. and Andersen et al. teach α -amylase variants and the combination of the specific variants disclosed with modification of other positions it would have been obvious to one of ordinary skill in the art to combine the modification at position 170 of Borchert et al. with the modification of position 49 taught by Andersen et al. One of skill in the art would be motivated to do so by the explicit teachings of both references of combining the disclosed variants with other variations known in the art.

Claims 41, 43, 44 46-49 and 51-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Andersen et al. (US PG-PUBS 2003/0129718) in view of Andersen et al. (US Patent 6,410,295).

Andersen et al. US PG-PUBS 2003/0129718) teach α -amylase variants in which the amino acid corresponding to position 170 of *Bacillus licheniformis* α -amylase (SEQ ID NO:8 of the instant application) in any Termamyl-like α -amylase is replaced with a different amino acid and also teach modification of other amino acid positions in combination. However, Andersen et al. do not

Art Unit: 1652

explicitly teach what amino acid position 170 should be replaced with. However, a skilled artisan would have found it obvious given the teaching of Andersen to modify this position to replace the naturally occurring amino acid with all other 19 naturally occurring amino acids. Furthermore, as inspection of the alignment of Termamyl-like α -amylases of Figure 1 of Andersen et al. shows that in some naturally occurring Termamyl-like α -amylases, this position is occupied with a glutamine residue, it would have been obvious to one of ordinary skill in the art to select glutamine as the amino acid to replace position 170 with as a skilled artisan would reasonably expect that the three-dimensional structure of Termamyl-like α -amylases would accommodate a glutamine at this position.

Andersen et al. (US Patent 6,410,295) teach α -amylase variants in which the amino acid corresponding to position 49 of *Bacillus licheniformis* α -amylase (SEQ ID NO:8 of the instant application) in any Termamyl-like α -amylase is replaced with a different amino acid preferably T49I (see column 6). Andersen et al. (US Patent 6,410,295) also teach modification of other amino acid positions. Andersen et al. further teach that a preferred parent alpha amylase is that of *Bacillus licheniformis* (see page 13, i.e., the alpha amylase of SEQ ID NO:8 herein)

Art Unit: 1652

As each of Andersen et al. (US PG-PUBS 2003/0129718) and Andersen et al. (US Patent 6,410,295) teach α -amylase variants and the combination of the specific variants disclosed with modification of other positions it would have been obvious to one of ordinary skill in the art to combine the modification at position 170 of Andersen et al. (US PG-PUBS 2003/0129718) with the modification of position 49 taught by Andersen et al. (US Patent 6,410,295). One of skill in the art would be motivated to do so by the explicit teachings of both references of combining the disclosed variants with other variations known in the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca E. Prouty whose telephone number is 571-272-0937. The examiner can normally be reached on Tuesday-Friday from 8 AM to 5 PM. The examiner can also be reached on alternate Mondays

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat Nashed, can be reached at (571) 272-0934. The fax phone number for this Group is 571-273-8300.

Art Unit: 1652

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rebecca Prouty/
Primary Examiner
Art Unit 1652